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By Rep. Tom Rooney (FL-16)

When I spoke with administrators, doctors and pharmacists at Charlotte County Regional Medical Center in the fall, they had one clear message: “You have to do something about drug shortages.”

Across the country, hospitals and physicians are facing critical shortages of common, life-saving drugs, like anesthetics, pain medications, chemotherapy drugs, intravenous antibiotics, nutritional drugs for patients who are unable to eat, and other drugs commonly used in intensive-care units. For example, in April, major cancer hospitals began rationing supplies of a drug used to treat leukemia after suppliers had production problems. The Food and Drug Administration (FDA) reports that drug shortages reached a record high of 178 in 2010 – a number that has nearly tripled since just 2005.

The medical staff at Charlotte County Regional Medical Center tells me that when there is shortage, they often have little or no warning, giving them no chance to prepare. These disruptions force doctors to delay or alter patient care plans. In many instances, no safe alternatives to these drugs exist, leaving patients with an increased risk of side effects and adverse drug interactions. As a result, doctors and hospital administrators are left to make difficult decisions about which patients need to be treated immediately and which must wait.

No patient should suffer because of a drug shortage that could have been prevented. That is why over the last several months I have worked with Representative Diana DeGette (D-CO) on a bipartisan bill to improve patient safety by reducing shortages of life-saving drugs.

The earlier doctors, suppliers and the FDA are able to communicate a potential drug

shortage, the better equipped they are to respond and possibly prevent a disruption from occurring. The FDA says that 38 shortages were prevented in 2010 thanks to early notification from manufacturers. However, under current law, manufacturers are only required to report discontinuances to the FDA if (1) they are the only manufacturer of the drug, and (2) the drug is deemed “medically necessary” by the FDA. There is no penalty for failing to report an expected shortage.

Our bill, the “Preserving Access to Life-Saving Medications Act,” would build on that law so that the FDA has more tools to mitigate shortages and notify doctors. Our legislation requires manufacturers of all prescription drugs, including complex medicines known as biologics, to notify the FDA of any discontinuance or interruption in the production of a drug at least six months advance. In the event of an unplanned interruption, our bill requires manufacturers to notify the FDA as soon as possible. The FDA can then work with manufacturers to address the disruption, while posting drug shortage information — including the expected duration of the interruption — on its website so that physicians and hospitals can prepare.

Because our goal is to increase access to needed drugs, we have worked carefully to ensure that the bill’s reporting requirements will not put undue burdens — which might increase costs for hospitals and patients — on manufacturers. Our hope is that by enhancing the alert system already in place, and improving communication between suppliers, physicians and the FDA, we can help mitigate and even prevent shortages.

Our bill has earned the support of the American Hospital Association, American Society of Clinical Oncology, American Society of Health-System Pharmacists, and Institute for Safe Medication Practices, as well as the generic drug manufacturer Hospira, Inc. These groups recognize that problem is only worsening, and we must quickly to help prevent sudden shortages of life-saving drugs.

Rooney represents District 16 in the U.S. House of Representatives.